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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,556	01/31/2001	Mitchell Anthony DeLong	79999	4976

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Catherine U. Brown  
The Proctor & Gamble Company  
Miami Valley Laboratories  
P.O. Box 538707  
Cincinnati, OH 45253-8707

EXAMINER
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WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/774,556

Applicant(s)

DELONG ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 16, 21-25, 35, 36, 40, 47 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 1-51 are pending. Claims 11-12, 16, 21-25, 35, 36, 40, 47 and 50 are withdrawn from consideration, as they are directed toward non-elected subject matter. The Amendment filed 11/13/03, amended claims 1, 3, 20-25 and 44.

Applicant's amendments to claims 20 and 44 are sufficient to overcome the 35 USC 112 rejections over these claims in the previous Office Action. Applicant's arguments of 11/13/03, are persuasive to overcome the 35 USC 112 rejections over the terms "a heterogeneous group" and a "substituted heterogeneous group" in the previous Office Action.

Applicant's amendment to claims 1 and 3 overcomes the 35 USC 102(a) rejection in the previous Office Action.

### ***Election/Restrictions***

Claims 11-12, 16, 21-25, 35, 36, 40, 47 and 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the Amendment filed 11/13/03. The Election/Restriction Requirement is hereby made final.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 13-15, 17-18, 20, 26-34, 37-39, 41-44, 48-49 are rejected under 35

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U.S.C. 103(a) as being unpatentable over DeLong (WO 99/50241).

The instant invention is directed toward a composition comprising an active ingredient of the prostaglandin of instant claim 1 and a carrier, and methods of applying the composition to the skin.

DeLong et al. teach C11 oxymyl and hydroxylamino prostaglandins useful as medicaments. Exemplified is a composition comprising 11-oxymyl-13,14-dihydro-17-(2-fluorophenyl) 17 trinor PGD, water, dextran 70, hydroxypropyl methylcellulose, sodium chloride, potassium chloride, disodium EDTA, benzalkonium chloride, and HCL and/or NaOH. The reference further exemplifies 11-oximyl-15-ethyl-18-phenyl-18-dinor-PGD<sub>2</sub> (Applicant's elected species), which meets the formula of the instant claims when W is (CH<sub>2</sub>)<sub>2</sub>, R<sub>1</sub> is CO<sub>2</sub>H, X is OH, Y is a bond, Z is an aromatic group, R<sub>5</sub> is C<sub>2</sub>H<sub>5</sub> and H, R<sub>6</sub> is OH and H, p is 3, q is 0, a is a double bond, c is a single bond, and b is a double bond. The compositions are taught as being administered systemically through transdermal, oral, parenteral, topical, and/or intranasal routes. Lotions, creams, gels, tablets, capsules and others are disclosed forms of the composition. The composition is disclosed as being administered daily for weeks or a month. The composition is disclosed for use in dermatological disorders. The reference lacks an exemplification of administering the composition to a mammal. See pages 13, 34-38.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify the composition of DeLong et al. as being administered to a mammal because DeLong et al. teach their composition as being administered to a mammal and because of the expectation of treating ocular disorders, hypertension, fertility control, nasal congestion, neurogenic bladder disorder, gastrointestinal disorders, dermatological disorders, and

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osteoporosis in mammals.

The claims 26-34, 37-39, 41-44, 48-49 are directed to a method of treating hair loss comprising administering to a mammal a composition comprising an active ingredient selected from the group consisting of oximyl and hydroxylamino prostaglandins having a specific functionality. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In *re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches administration to a mammal of compositions containing the same components as instantly claimed, which would inherently treat hair loss as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

While the limitation of claim 18 is not explicitly taught, it would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the prostaglandins of DeLong in the amount recited in instant claim 18 because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In *re Aller*, 105 USPQ 233.

Claims 19, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLong et al. as applied to claims 1-10, 13-15, 17-18, 20, 26-34, 37-39, 40-44, 48-49 above, and

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further in view of Nathanson (5,500,230).

DeLong et al. is applied as discussed above. The composition lacks a hair growth stimulant.

Nathanson teaches a method for the treatment of glaucoma with nitrogen containing guanylate cycloase activators. Exemplified is a method of treating glaucoma in an individual comprising systemically administering a therapeutically effective amount of minoxidil. See Col. 18, lines 33-line 65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the minoxidil of Nathanson to the composition of DeLong et al. because both Nathanson and DeLong et al. are directed toward treating glaucoma and it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. In re Kerkoven, 205 USPQ 1069 (CCPA 1980).

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeLong et al. as applied to claims 1-10, 13-15, 17-18, 20, 26-34, 37-39, 41-44, 48-49 above, and further in view of Johnstone (6,262,105).

DeLong et al. is applied as discussed above. The reference lacks a method of applying their composition to growing hair.

Johnstone teaches a method of enhancing hair growth comprising topically applying a composition comprising prostaglandins to the scalp and hair. It is further disclosed that prostaglandins useful in glaucoma treatment are useful in enhancing hair growth. See Col. 1, line 25-Col. 5, line 34; Col. 17.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of DeLong et al. as being applied to growing hair, as disclosed by Johnstone, because a) DeLong et al. teach their compositions, which comprise prostaglandins, for use in treating dermatological disorders; b) Johnstone teaches that prostaglandins, such as those that treat glaucoma, are also useful for enhancing the growth the hair, and the prostaglandins of DeLong are disclosed as useful in treating glaucoma; thus, one of skill in the art would be motivated to apply the composition of DeLong et al. to growing hair because of the expectation of enhancing hair growth via vasodilation.

#### ***Response to Arguments***

Applicant argues, “present claims 18, 26-34, 37-39, 41-44 and 48-49 all relate to methods of treating hair loss in a mammal”. This argument is not persuasive. First, it is respectfully pointed out that instant claim 18 is not directed toward a method, but is directed toward a composition. Second, while claims 26-34, 37-39, 41-44, 48-49 are directed to a method of treating hair loss comprising administering to a mammal a composition comprising an active ingredient selected from the group consisting of oximyl and hydroxylamino prostaglandins having a specific functionality, it is respectfully pointed out that any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches

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administration to a mammal of compositions containing the same components as instantly claimed, which would inherently treat hair loss as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

Applicant argues, “unlike Delong, the compositions and methods of the present invention are not administered systemically. Rather, the compositions and methods of the present invention are administered locally and, in fact, are adapted to minimize systemic absorption”. This argument is not persuasive, as it is not commensurate in scope with the instant claims, which contain no limitations to the means by which the composition is administered.

Applicant argues, “The Applicants submit that, indeed, the subject compositions of Delong and Nathanson are both disclosed to be useful in the treatment of glaucoma (i.e., useful for the same purpose). However, the claims of the present application are not directed to the treatment of glaucoma. . . although the compositions of Delong and Nathanson are useful for the same purpose, it would not have been obvious to a person of ordinary skill in the art to combine said compositions to be used for a materially different purpose”. This argument is not persuasive. The Examiner respectfully directs the Applicant to MPEP 2144, “Rationale Different From Applicant’s is Permissible”, which states, “the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant”.

Applicant argues, “contrary to the disclosure of Johnstone, only a single group of prostaglandins, namely the Prostaglandin F group to which the present application lays claim,



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demonstrate meaningful activity in the treatment of mammalian hair conditions. The Applicants further submit that Johnstone provides no guidance to a person of ordinary skill in the art as to which of the numerous prostaglandin groups disclosed therein as being useful in the treatment of glaucoma, are also useful in the treatment of mammalian hair conditions". This argument is not persuasive. First, it is respectfully pointed out that Applicant has provided no evidence to back up his assertion that only Prostglandin F has meaningful activity in mammalian hair conditions. Second, it is respectfully pointed out that Johnstone is directed not to all prostaglandins, but to A, E and F. Third, it is respectfully pointed out that Johnstone states that it is established in the art that prostaglandins that treat glaucoma are also used to treat hair loss. Thus, one of skill in the art would be motivated to look toward prostaglandins used to treat glaucoma as useful active agents for treating hair loss.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw



**SREENI PADMANABHAN**  
SUPERVISORY PATENT EXAMINER